EXHIBIT A

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June 3, 2008

Debbie L. Berman Jenner & Block LLP 330 N. Wabash Ave. Chicago, IL 60611

Re: National Pediculosis Association

Dear Ms. Berman:

It has come to my attention that your client, the National Pediculosis Association ("NPA"), has made, and continues to make, false statements in connection with Food & Drug Administration filings regarding adverse drug reactions to lindane medications. The NPA's practice in submitting these reports is dishonest, unethical, and constitutes a fraud on the FDA, the public, and Morton Grove Pharmaceuticals. This behavior has injured my client Morton Grove Pharmaceuticals, Inc. ("MGP"), the sole U.S. distributor of lindane medications, well beyond the allegations in our present litigation.

Specifically, the NPA has filed and continues to file with the FDA various adverse drug reactions relating to Lindane medications wherein it claims to be reporting as a health professional. These reports are often serious and assert various outcomes from congenital anomalies to disability and death.

The NPA's submission of these forms as a "health professional" is fraudulent. First, the NPA is <u>not</u> a "health professional" under definitions promulgated by the FDA. In completing MedWatch reports, the FDA directs that one should "indicate whether you are a health professional (e.g. physician, pharmacist, nurse, etc.) or not." The information is specifically sought by the FDA because of the health care professional's proximity to and typical involvement in the actual adverse event and their unique ability to associate cause and effect. The FDA has even indicated a preference that consumers have an actual health professional fill

General Instructions for Completing the Internet MedWatch form, available at https://www.accessdata.fda.gov/scripts/medwatch/ (last updated Oct. 2005).

WINSTON & STRAWN LLP

Debbie L. Berman June 3, 2008 Page 2

out the form: "Note for consumers: If possible, please take the 3500 form to your health professional (e.g., doctor or pharmacist) so that information based on your medical record that can help in the evaluation of your report will be provided.²"

Nowhere has the FDA found it appropriate to have a third party that is not involved in treatment, and which does not even bring qualified medical professionals to bear on the substance of these reports, file them as medical professionals.

While the NPA has filed hundreds of adverse event reports as health care professionals, we understand that your client does not employ a single physician, pharmacist, or nurse; nor is its Executive Director a licensed health care professional.

Further, the NPA's Board of Directors is not comprised of any health care professionals.

In addition, the NPA's own documents make evident that *no* health professional was involved in the submission of these reports, *no* health professional answered patient questions or evaluated patient conditions, and *no* health professional assessed whether the information submitted on the forms is even arguably accurate—yet the NPA made hundreds of filings as if such a review was undertaken.

Not only are the MedWatch forms submitted by the NPA misleading with respect to the "health professional" designation, but the very lack of medical professional review infects their substance. For example, a report produced at NPA 73132 describes the problem as "BROKE OUT ON HANDS ARMS SHOULDERS,& BELTLINE . . ." but the NPA filed the report with the FDA indicating a "disability" should be attributed to this problem. Much the same, a report produced at NPA 73239, notes "conjunctivitis" and "rash," but the NPA submitted the report with a "disability" and "life threatening" outcome attributed to the product. Neither of these reports are atypical of those submitted by the NPA, and neither indicate that a doctor or other health professional diagnosed lindane as the cause of medical problems, yet the NPA's report makes just such a link.

As for the significance of their impact, your client has even argued that its practice of its submitting MedWatch forms—which we believe are largely fraudulent—resulted in the FDA's 1996 alert on lindane medications and the FDA's 2003 black box warning (see NPA 23113 and NPA 04082). Indeed, the NPA has put no safeguards into place to prevent, or even minimize, double-reporting to the FDA (given that there have only been 488 adverse events reported to the FDA from 1951 through 2002, this is a significant huge concern).

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WINSTON & STRAWN LLP

Debbie L. Berman June 3, 2008 Page 3

It is unclear why the NPA has even injected itself into the reporting process when adverse events can easily be submitted online through the FDA's website without making such false statements (*see* https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm).

On behalf of my client Morton Grove Pharmaceuticals, Inc., we demand that the NPA cease and desist this activity immediately. MGP makes this claim with full reservation of all rights against the NPA.

Sincerely,

W. Gordon Dobie

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